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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,774	11/08/2000	Alessandro Sette	18623006240	3936

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/709,774

Applicant(s)

SETTE ET AL.

Examin r

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this c mmunicati n app ars on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-65 is/are pending in the application.
- 4a) Of the above claim(s) 27-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1644

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 18-26 in Paper No. 12, filed 10-03-02, is acknowledged. The traversal is on the ground(s) that examination of the claims in Groups I-V in the instant application would not create an undue burden. This is not found persuasive because Groups I-V are each distinct for the reasons given in the restriction mailed 7-2-02 (Paper No. 12), and as such have acquired a separate status in the art because of their recognized divergent subject matter. MPEP 803 states that: "For the purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation, either separate classification, separate status in the art, or different field of search. Because a search in the non-patent literature of Group I would not be co-extensive with a search of the non-elected groups (Groups II-V), an examination and search of Groups I-V in a single application would constitute a serious undue burden on the Examiner, and therefore, restriction for examination purposes as indicated is proper.

Applicant's election of the species of AKXVAAWTLKAAA in Paper No. 14, filed 1-14-03, is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 27-65 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12, filed 10-13-02.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Priority*

Applicant is not entitled to priority to 08/305,871 due to lack of support for the pending claims. Applicant is invited to point out support for instant claims 18-26.

Art Unit: 1644

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). See the alterations in the date section after the name of Inventor Howard Grey.

### ***Specification***

The specification is objected to because it does not support the claims added in the amendment filed 11-8-00 Paper No. 1.5. The added material which is not supported by the original disclosure is as follows: a polynucleotide encoding a fusion protein comprising an immunogenic peptide, a native protein or a particle, and at least one pan DR binding peptide selected from the formula  $R_1R_2R_3R_4R_5$ .

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant disclosure on page 11 that recombinant DNA technology can be used to make fusion proteins which encode an immunogenic peptide of interest, and that for expression of fusion proteins, the coding sequence will be provided with be ligated into suitable vectors and transformed into hosts suitable for expression of the encoded fusion protein, does not provide adequate written description for the genus of a polynucleotide encoding a fusion protein comprising an immunogenic peptide, a native protein or a particle, and at least one pan DR binding peptide selected from the formula  $R_1R_2R_3R_4R_5$ , as recited in claim 18 and dependent claims 19-26.

It is noted by the examiner that though the claimed invention is directed to a polynucleotide encoding a fusion protein, and not cDNA, the principle of the following still

Art Unit: 1644

holds for the genus of said polynucleotide encoding a fusion protein : a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Accordingly, the lack of a disclosure of one species of a genus is not equivalent to a representative number of species. Also, the structural features common to the genus of polynucleotides encoding a fusion protein, wherein said fusion protein comprises a native protein fragment or a particle, are not disclosed. Therefore, one of skill would not be able to discern which polynucleotides encoding a fusion protein wherein said fusion protein comprises a native protein fragment or a particle proteins, and at least one pan DR binding peptide selected from the formula  $R_1R_2R_3R_4R_5$ , without further description from the specification. Therefore, the disclosure on page 11 that recombinant DNA technology can be used to make fusion proteins is not sufficient to provide adequate written description for the breadth of the claimed genus of peptides and proteins.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 18-26 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 9958658.

WO 9958658 teaches that the coding sequences of PADRE (pan-DR epitope) universal Th cell epitope and an endoplasmic reticulum-translocating signal sequence (mouse IG.kappa. signal peptide) were fused with the coding sequence of the above nine CTL epitopes in the plasmid minigene and expressed from a plasmid vector to stimulate the immune response, see entire patent including the Abstract. '658 teaches that the pan DR epitope has the sequence of AKXVAAWTLKAAA, and that the pan DR epitope can be comprise two or more pan DR epitopes and that said epitopes can be heterologous peptides, see entire patent, especially pages 7-8. '658 teaches that the encoded immunogenic peptide can comprise a T helper peptide and/or a CTL inducing peptide, and/or an antibody inducing peptide, see entire patent, especially Page 16 and Tables 1-8. Therefore, the references anticipate the claimed invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.,

Patent Examiner,

Group 1640,

March 23, 2003

*Amy DeCloux*  
3-23-03